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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,228

07/31/2003

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50623.251

1730

45159 7590 11/25/2008  
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EXAMINER

LIN, JAMES

ART UNIT

PAPER NUMBER

1792

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/631,228	<b>Applicant(s)</b> PATHAK ET AL.	
	<b>Examiner</b> Jimmy Lin	<b>Art Unit</b> 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-14,16-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) 7,11,12,14 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8-10,13,16-18,23-29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 18, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although a variety of fluids are exemplified in the specification as representative fluids (see pg. 8-9), it has not been shown that Applicant had possession of using the claimed fluids, with the exception of water, as a fluid to physically entrap without dissolving the impurity. The fluids are generically listed in the specification without indication as to whether the Applicant had intended them to be used for dissolving or entrapping. Thus, the claims present new matter.

### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 3-5, 8-10, 31-33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan et al. (U.S. Publication 2004/0063663) in view of Inoue et al. (U.S. Patent 5,762,944), Hughes et al. (U.S. Patent 5,756,659), and Goodson et al. (U.S. Patent No. 4,117,714).

Buchanan discloses a method of making a carrier polymer that is used to coat the surface of a stent to provide controlled and sustained release of an anticoagulant drug at the preferred site [0065]. The coating can be formed by putting the carrier polymer along with the other additives into a twin screw extruder [0051]. The polymer can be a thermoplastic material [0059].

Buchanan does not teach introducing a fluid into the extruder and removing at least a volume of the fluid from the extruder such that an impurity is at least partially removed with the fluid. Inoue teaches a method of making a coating for a stent, wherein the coating comprises a polymer (col. 3, lines 1-31). Inoue recognizes the need to wash the polymer to remove impurities in the method of making medical devices such as a stent. The impurities can include a solvent, an unreacted monomer, and an impurity (col. 6, lines 38-43). Hughes teaches a method of removing impurities, such as unreacted monomer, solvent, and thermally unstable species, from a molten polymer inside a twin-screw extruder. A stripping agent is introduced into the polymer melt stream and the polymer/stripping agent mixture is homogenized in a mixing zone. At least some of the stripping agent and impurities are removed from the polymer (col. 3, lines 10-33; Fig. 2). 3) The temperature of each extruder zone is controlled by a temperature controller and resistance heaters that are monitored by means of a series of thermocouples 29-36 (col. 3, lines 16-20). The temperatures of the thermocouples range from 112 to 240 °C (Table 6). It would have been obvious to one of ordinary skill in the art at the time of invention to have introduced a fluid into the extruder to have removed impurities from the polymer of Buchanan because Inoue recognizes the need to remove impurities in a method of making a material for a medical device and because Hughes teaches that such an in-situ process is suitable in the art of removing impurities from a polymer. The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

Buchanan, Inoue, and Hughes do not explicitly teach that the fluid is a type to physically entrap the impurity without dissolving the impurity. However, Goodson teaches that there are only a finite number of identified, predictable potential solutions in the method of removing impurities. Specifically, Goodson teaches that an impurity can be removed from a medium by either dissolving or entrapping the impurity in a fluid (col. 3, lines 39-42). One of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success (see MPEP 2145.X.B.). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid to physically entrap the impurity, as opposed to a fluid to dissolve the impurity, in the method removing the impurity of Buchanan with a reasonable expectation of success and with predictable results.

Claim 3: Buchanan teaches that a single screw extruder can also be used [0051].

Claim 4-5: Buchanan teaches that the polymer must be melted in the extruder [0051].

Claim 8: Hughes teaches that a second stripping agent can be introduced to the extruder, wherein the stripping agent removes an impurity from the polymer (col. 3, lines 33-45).

Claim 9: Buchanan teaches that a suitable thermoplastic can be polyethylene-vinyl acetate copolymer (i.e., an ethylene-vinyl acetate copolymer) [0059].

Claim 10: Inoue teaches that a suitable fluid can be water (col. 6, lines 38-43).

Claim 31: Hughes teaches that two fluids can be used to remove impurities (col. 3, lines 23-38).

Buchanan and Hughes do not explicitly teach that using a first fluid acting as a solvent for the impurity and a second fluid acting as a non-solvent for the impurity and that the first fluid and the second fluid are not the same. However, Goodson does recognize that removing impurities using a dissolving mechanism (i.e., solvent) or an entrapment mechanism (i.e., non-solvent) were both operable methods. One of ordinary skill in the art would have used either one of the mechanisms or a combination of both in the process of removing an impurity with predictable results because the use of known potential solutions would have been obvious. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a solvent as the first fluid in combination with a non-solvent as the second fluid with a reasonable expectation of success.

Claims 32-33,35: Hughes teaches that the extruder temperature ranges from 112 to 240 °C (Table 6). Such temperatures are greater than the boiling temperatures of the fluids.

5. Claims 13, 16-18, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663, Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1 above, and further in view of Berg et al. (EP 0623354).

Buchanan, Inoue, and Hughes are discussed above, but do not explicitly teach that the polymer can be combined with a solvent. However, Berg teaches that a solution comprising a polymer and solvent can be applied to the coating of a stent and then evaporating the solvent (abstract). The selection of something based on its known suitability for its intended use has been held to support a prima facie case of obviousness. *Sinclair & Carroll Co. v. Interchemical*

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Corp., 325 U.S. 327, 65 USPQ 297 (1945). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the polymer of Buchanan, Inoue, and Hughes in a solvent solution and then evaporating the solvent because Berg teaches that such a coating method is suitable in the art of coating a stent.

Claim 36: Buchanan, Inoue, and Hughes do not explicitly teach introducing a second fluid that is of a type that dissolves the impurity. However, Hughes does teach that a second fluid is introduced to remove impurities and Goodson teaches that there are only a limited, potential solutions for removing impurities from a medium. One of ordinary skill in the art would have recognized that the use of a fluid having the properties either to entrap or to dissolve an impurity as the particular second fluid would have been operable and that the use of one over the other would have yielded predictable results. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to have used a fluid that is of a type that dissolves an impurity, as opposed to one that entraps an impurity, as the particular second fluid of Hughes with a reasonable expectation of success.

Claims 16-18 and 37 are rejected for substantially the same reasons as claims 4-5, 9-10, and 35 above.

6. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714, as applied to claim 1, and further in view of Ainpour (U.S. Patent No. 4,526,579).

Buchanan, Inoue, Hughes, and Goodson are discussed above, but do not explicitly teach that the fluid is selected from FLUX REMOVER AMS, dimethyl acetamide, dimethyl formamide, dimethyl sulfoxide, and combinations thereof. However, Ainpour teaches that it was well known to use dimethyl formamide or dimethyl sulfoxide to remove residual monomers from a polymeric material (col. 2, line 60-col. 3, line 11). Ainpour teaches that the polymer can be used for implantable medical devices such as catheters (col. 2, lines 25-27). Because Ainpour teaches that such fluids were operable in the art for removing monomers, it would have been obvious to one of ordinary skill in the art at the time of invention to have used dimethyl formamide or dimethyl sulfoxide as the particular fluid to remove the residual monomers of Buchanan with a reasonable expectation of success.

7. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714 as applied to claim 31 above, and further in view of Chudzik et al. (U.S. Patent No. 6,156,345).

Buchanan does not explicitly teach that the polymer can be poly(vinylidene fluoride-co-hexafluoropropene or poly(butyl methacrylate). However, Buchanan does teach that the polymeric material suitable for use in the invention is not limited [0059]. Accordingly, Chudzik teaches that poly(butyl methacrylate) was a well known biostable polymer that can be used for drug delivery devices (col. 1, lines 15-19; col. 5, lines 37-42). Because Buchanan does not limit the choice of the polymeric material and because Chudzik teaches that such polymeric materials were operable for use in drug delivery systems, it would have been obvious to one of ordinary skill in the art at the time of invention to have used poly(butyl methacrylate) as the particular polymeric material of Buchanan with a reasonable expectation of success.

#### ***Response to Arguments***

8. Applicant's arguments, see pg. 11-12, filed 8/25/2008, with respect to the rejection(s) of claim(s) 31-34 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Buchanan '663 in view of Inoue '944, Hughes '659, and Goodson '714.

9. Applicant's arguments, see pg. 13-14, filed 8/25/2008, with respect to the rejection(s) of claim(s) 23-27 and 29 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Buchanan '663 in view of Inoue '944, Hughes '659, Goodson '714, and Ainpour '579.

10. Applicant's arguments filed 8/25/2008 have been fully considered but they are not persuasive.

Rejections under 35 U.S.C. 112

Applicant argues on pg. 9-10 that Applicants have demonstrated that at least one of the fluids is of the type to physically entrap an impurity without dissolving the impurity. However, the possession of one of the many claimed species does not demonstrate possession of the full scope of the claim because Applicant has not shown possession of the other claimed species.

Applicant argues on pg. 10 that the standard for a §112, first paragraph rejection is whether the description of the invention in the specification can “enable any person skilled in the art . . . to make and use the same”. However, §112, first paragraph also requires that the “specification shall contain a written description of the invention”. This requirement is separate and distinct from the enablement requirement. The essential goal of the description of the invention requirement is to clearly convey the information that Applicant has invented the subject matter which is claimed. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that Applicant had possession of the claimed invention (see MPEP 2163).

Applicant argues on pg. 10 that using Examiner’s criteria to show written description, Applicants would need to identify every type of possible impurity and every type of solvent and non-solvent pairing. Applicant further argues that this is clearly an impossible task and is not the standard under §112, first paragraph. However, Applicant just needs to show possession of all of the claimed fluids being used as a non-solvent.

#### Rejections under 35 U.S.C. 103

Applicant argues on pg. 12-13 that Goodson teaches “the air 18 is scrubbed as it passes through and above the rotating film 20 and any impurities therein are dissolved or entrapped in the water film” and that this statement at most teaches that impurities may be removed from air by passing them through a film of water. Applicant argues that there are several different ways to remove impurities using conventional and unconventional ways, including CO<sub>2</sub> extraction, using enzymes, using bacteria, and using settling technique. However, Goodson teaches that either a dissolving mechanism or an entrapping mechanism can be used to remove impurities with a fluid. One of ordinary skill in the art would have recognized that both mechanisms would have been operable for removing an impurity and that the use of either one or a combination of



both would have been operable. The use of known potential solutions would have been an obvious modification. One of ordinary skill in the art would have used the solutions of Goodson with predictable results and with a reasonable expectation of success.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iguchi et al. (U.S. Patent 5,756,553) recognizes the need to remove impurities from polymers used for medical devices (col. 4, line 66 – col. 5, line 2).

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jimmy Lin whose telephone number is (571)272-8902. The examiner can normally be reached on Monday thru Friday 8AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jimmy Lin/  
Examiner, Art Unit 1792

/Timothy H Meeks/  
Supervisory Patent Examiner, Art Unit  
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